

§ 206.7

not necessarily, in association with one or more other ingredients.

Embossed means imprinted with a mark raised above the dosage form surface.

Engraved means imprinted with a code that is cut into the dosage form surface after it has been completed.

Imprinted means marked with an identification code by means of embossing, debossing, engraving, or printing with ink.

Manufacturer means the manufacturer as described in §§ 201.1 and 600.3(t) of this chapter.

Solid oral dosage form means capsules, tablets, or similar drug products intended for oral use.

§ 206.7 Exemptions.

(a) The following classes of drug products are exempt from requirements of this part:

(1) Drug products intended for use in a clinical investigation under section 505(i) of the act, but not including drugs distributed under a treatment IND under part 312 of this chapter or distributed as part of a nonconcurrently controlled study. Placebos intended for use in a clinical investigation are exempt from the requirements of this part if they are designed to copy the active drug products used in that investigation.

(2) Drugs, other than reference listed drugs, intended for use in bioequivalence studies.

(3) Drugs that are extemporaneously compounded by a licensed pharmacist, upon receipt of a valid prescription for an individual patient from a practitioner licensed by law to prescribe or administer drugs, to be used solely by the patient for whom they are prescribed.

(4) Radiopharmaceutical drug products.

(b) Exemption of drugs because of size or unique physical characteristics:

(1) For a drug subject to premarket approval, FDA may provide an exemption from the requirements of § 206.10 upon a showing that the product's size, shape, texture, or other physical characteristics make imprinting technologically infeasible or impossible.

(i) Exemption requests for products with approved applications shall be

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made in writing to the appropriate review division in the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. If FDA denies the request, the holder of the approved application will have 1 year after the date of an agency denial to imprint the drug product.

(ii) Exemption requests for products that have not yet received approval shall be made in writing to the appropriate review division in CDER or CBER.

(2) Any product not subject to premarket approval is exempt from the requirement of § 206.10 if, based on the product's size, shape, texture, or other physical characteristics, the manufacturer or distributor of the product is prepared to demonstrate that imprinting the dosage form is technologically infeasible or impossible.

(c) For drugs that are administered solely in controlled health care settings and not provided to patients for self-administration, sponsors may submit requests for exemptions from the requirements of this rule. Controlled settings include physicians' offices and other health care facilities. Exemption requests should be submitted in writing to the appropriate review division in CDER or CBER.

§ 206.10 Code imprint required.

(a) Unless exempted under § 206.7, no drug product in solid oral dosage form may be introduced or delivered for introduction into interstate commerce unless it is clearly marked or imprinted with a code imprint that, in conjunction with the product's size, shape, and color, permits the unique identification of the drug product and the manufacturer or distributor of the product. Identification of the drug product requires identification of its active ingredients and its dosage strength. Inclusion of a letter or number in the imprint, while not required, is encouraged as a more effective means of identification than a symbol or logo by itself. Homeopathic drug products are required only to bear an imprint that identifies the manufacturer and their homeopathic nature.